

What is claimed is:

1. A composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, consisting essentially of:

(a) from about 5 $\mu\text{g/ml}$ to about 5 mg/ml of a corticosteroid in dissolved form,

(b) from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants is greater than about 10, and

(c) at least about 70 weight percent aqueous phase.

2. The composition of claim 1 wherein the high-HLB surfactant component comprises at least 50% by weight of an ethoxylated derivative of vitamin E, a polyethylene glycol fatty acid ester, or a mixture thereof.

3. The composition of claim 2 wherein the high-HLB surfactant component comprises an ethoxylated derivative of vitamin E.

4. The composition of claim 2 wherein the high-HLB surfactant component comprises a polyethylene glycol fatty acid ester.

5. The composition of claim 2 wherein the corticosteroid comprises beclomethasone dipropionate.

6. The composition of claim 2 wherein the corticosteroid comprises budesonide.

7. The composition of claim 2 wherein the corticosteroid comprises triamcinolone acetonide.

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8. The composition of claim 2 wherein the corticosteroid comprises fluticasone propionate.

9. The composition of claim 2 wherein the corticosteroid comprises flunisolide.

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10. The composition of claim 2 wherein the high-HLB surfactant component comprises tocopheryl polyethylene glycol 1000 succinate.

11. The composition of claim 2 wherein the high-HLB surfactant component comprises polyethylene glycol hydroxystearate.

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12. A composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, comprising:

(a) from about 5 μ g/ml to about 5 mg/ml of a corticosteroid in dissolved form,

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(b) from about 0.1 to about 20 percent by weight of a high-HLB surfactant component wherein the HLB of the surfactants is greater than about 10, and wherein the high-HLB surfactant component comprises an ethoxylated derivative of vitamin E, a polyethylene glycol fatty acid ester, or a mixture thereof; and

(c) at least about 70 weight percent aqueous phase.

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13. The composition of claim 12 wherein the high-HLB surfactant component comprises an ethoxylated derivative of vitamin E.

14. The composition of claim 12 wherein the high-HLB surfactant component comprises a polyethylene glycol fatty acid ester.

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15. The composition of claim 12 further comprising from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable cosolvent comprising propylene glycol, polyethylene glycol having a molecular weight between about 200 and 4000, glycerol, ethoxydiglycol, glycofurol, and ethanol, or a combination thereof.

5 16. The composition of claim 12 further comprising from about 0.1 to about 3 percent by weight of a low HLB surfactant having an HLB below about 8.

17. The composition of claim 12 further comprising from about 0.1 to about 3 percent by weight of an oil.

10 18. A method for administering a therapeutic dosage of a corticosteroid to the respiratory tract, comprising:

(a) providing a corticosteroid composition comprising:

(1) from about 5 $\mu\text{g/ml}$ to about 5 mg/ml of a corticosteroid in dissolved form,

15 (2) from about 0.1 to about 20 percent by weight of a high-HLB surfactant component wherein the HLB of the surfactants is greater than about 10, and wherein the high-HLB surfactant component comprises an ethoxylated derivative of vitamin E, a polyethylene glycol fatty acid ester, or a mixture thereof; and

(3) at least about 70 weight percent aqueous phase;

20 (b) aerosolizing the corticosteroid composition in a nebulizer; and

(c) administering a therapeutic effective dosage of the aerosol of the corticosteroid composition by inhalation.

19. The method of claim 18 wherein the corticosteroid composition
25 consists essentially of said corticosteroid, said aqueous phase, and said high-HLB surfactant.

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20. A method for administering a therapeutic dosage of a corticosteroid to the nasal passage, comprising:

(a) providing a corticosteroid composition comprising:

5 (1) from about 50 $\mu\text{g/ml}$ to about 10 mg/ml of a corticosteroid in dissolved form,

(2) from about 0.1 to about 20 percent by weight of a high-HLB surfactant component wherein the HLB of the surfactants is greater than about 10, and wherein the high-HLB surfactant component comprises an ethoxylated derivative of vitamin E, a polyethylene glycol fatty acid ester, or a mixture thereof; and

10 (3) at least about 70 weight percent aqueous phase;

(b) administering a therapeutic effective dosage of the corticosteroid composition by nasal inhalation.

21. A method of preparing a diluted corticosteroid composition containing the corticosteroid in a relatively high, dissolved concentration, comprising:

15 (a) dissolving a corticosteroid compound into a molten pharmaceutically acceptable high-HLB surfactant component, wherein the HLB of the high-HLB surfactant component is greater than about 10;

(b) subsequently blending the molten high-HLB surfactant component containing the dissolved corticosteroid with an aqueous phase,

20 wherein the aqueous phase is present in an amount of at least about 70 weight percent, and the high-HLB surfactant component is present in an amount of from about 0.1 to about 20 weight percent of the diluted corticosteroid composition.